



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/727,123 | 12/02/2003 | Raymond E. Idcker | 5656.34 | 4773 |

7590 06/15/2006

Julie H. Richardson
Myers Bigel Sibley & Sajovec, P.A.
P.O. Box 37428
Raleigh, NC 27627

| |
|----------|
| EXAMINER |
|----------|

BERTRAM, ERIC D

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

3766

DATE MAILED: 06/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

88

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/727,123 | Applicant(s) IDEKER ET AL. | |
| | Examiner Eric D. Bertram | Art Unit 3766 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 1-25, 29, 30, 34-40, 46-48, 50 and 53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-28, 31-33, 41-45, 49, 51 and 52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 December 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>12/2/03, 4/29/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Species B and Sub-species i in the reply filed on 6/8/2006 is acknowledged. The traversal is on the ground(s) that the special technical features of the different embodiments are such that it would not cause an undue burden on the Examiner to search and examine all of the original claims. This is not found persuasive because the different species would require different fields of search (see MPEP § 808.02). Specifically, the cardiac activity sensor and the electrical stimulus device found in the disclosed species would necessitate the use of divergent searches in order to properly and completely examine the claims.

The requirement is still deemed proper and is therefore made FINAL.

2. The applicant has submitted that claims 1-9, 17, 18, 25, 26-28, 31-33, 41-45 and 49-52 all read on the elected species. However, as shown in figure 4B, an electrical stimulus device is not included in the elected species. As a result, claims 1-9, 17, 18, 25 and 50 are withdrawn from consideration as being drawn to a non-elected species since these claims require the use of an electrical stimulus device.

3. Claims 26-28, 31-33, 41-45, 49, 51 and 52 read on the elected species and will be examined in this detailed action.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on 12/2/2003 and 4/29/2005 were filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Specification

5. The disclosure is objected to because of the following informalities: on page 1, lines 18 of the specification, the word "proximate" immediately following "compressing the heart" should be deleted.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 42 recites the limitation "the at least one sensing electrode" in line 5 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 26, 27, 41 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Gelfand et al. (US 5,772,613, hereinafter Gelfand). Gelfand discloses a method for performing chest compressions where an ECG instrument 123 is employed to sense the intrinsic spontaneous heart activity of a patient in real-time (Col. 9, lines 1-

Art Unit: 3766

3). Based on this sensed activity, compression is applied using a CPR vest 102 that is timed to be delivered at a favorable time to improve cardiac function (Col. 9, lines 3-10).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 3766

13. Claims 28 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelfand in view of Prutchi et al (US 6,198,968, hereinafter Prutchi). Gelfand, as described above, discloses the applicant's basic invention with the exception of timing the compression so that it does not overlap with the T-wave portion of a spontaneous intrinsic cardiac cycle. Attention is directed to the secondary reference of Prutchi, which discloses a implantable cardiac pacer and method. While Prutchi does not specifically discuss mechanical stimulation of the heart, it deals with the analogous issue of electrical stimulation of the heart for increased cardiac function. Prutchi discloses that there is a vulnerable portion in the cardiac cycle that encompasses the length of the T-wave. As a result, Prutchi teaches avoiding stimulating the heart during the T-wave (Col. 3, lines 1-23). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Gelfand by avoiding stimulation of the heart during the T-wave as taught by Prutchi since application at this time may result in fibrillation of the heart.

14. Claims 31-33, 44 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelfand in view of Halperin et al. (US 6,390,996, hereinafter Halperin). Gelfand, as described above, discloses the applicant's basic invention with the exception of using closed chest manual compression of the heart. While the use of closed chest manual compression is notoriously old and well known in the art, attention is also directed to the secondary reference of Halperin, which discloses the use of closed chest manual compressions based on sensed ECG patterns (Col. 2, line 62-Col. 3, line 17). Therefore, it would have been obvious to substitute the manual

Art Unit: 3766

compressions of Halperin for the automated compressions of Gelfand in order to allow the therapy to be applied by hand quickly and without having to wait to apply the vest of Gelfand.

15. Regarding claims 32, 44 and 45, Halperin discloses the use of an audible indicator 18 for signaling the correct time to apply compression (Col. 5, lines 60-65). Furthermore, Halperin discloses a monitor that displays the real-time ECG of the patient so that the physician may correctly apply compressions (Col. 11, lines 50-58). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the system of Gelfand by adding the audible and visual indicators of Halperin in order to easily and conveniently convey important information to the physician.

16. Claims 49 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gelfand. Gelfand, as described above, disclose a method and apparatus completing all of the instructions contained in claims 49 and 51. Gelfand does not, however, specifically disclose the use of a computer-readable medium loaded with code containing the instructions. Although Gelfand does not disclose the medium, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to include the medium since it is old and well known that a processor cannot function without first being programmed by a medium containing the necessary instructions.

17. Claim 52 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gelfand in view of Halperin. Gelfand, as modified above, disclose a method and apparatus

Art Unit: 3766

completing all of the instructions contained in claim 52. Gelfand does not, however, specifically disclose the use of a computer-readable medium loaded with code containing the instructions. Although Gelfand does not disclose the medium, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to include the medium since it is old and well known that a processor cannot function without first being programmed by a medium containing the necessary instructions.


Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3766

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Robert E. Pezzuto
Supervisory Patent Examiner
Art Unit 3766

Eric D. Bertram
Examiner
Art Unit 3766

EDB